

**REMARKS****Claim Rejections****35 U.S.C. §112 Rejections****35 U.S.C. §112, second paragraph**

The Examiner has rejected Claims 13-25 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, regarding Claims 13-16, the Examiner asserts that the terms “flexible” and “inflexible” are indefinite because it is allegedly “unclear what structure or material is considered to be ‘flexible’ or ‘inflexible’” such that “one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.” The Examiner further asserts that the terms “the outer side” and “the position” in Claim 13, the terms “the flexible portions” and “the inflexible portion” in Claim 14, the terms “the area” and “portions” in Claims 15 and 16 and the term “the inside” in Claim 23 allegedly lack proper antecedent basis. Moreover, the Examiner asserts that Claim 18 allegedly appears to be “incomplete or unfinished.”

Applicant respectfully asserts that Claim 16 has been cancelled and Claims 13-15 and 17-25 have been amended to traverse the rejections of the Patent Office.

**35 U.S.C. §102 and §103 Rejections**

The Examiner has rejected Claims 13, 17 and 18 under 35 U.S.C. §102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent 5,219,324 to Charles Hall (hereinafter “Hall”), Claim 14 under 35 U.S.C. §103(a) as allegedly being unpatentable over Hall as applied to Claims 13, 17 and 18 hereinabove, and further in view of the publication WO 95/31950, Claim 15 under 35 U.S.C. §103(a) as allegedly being unpatentable over Hall as applied to Claims 13, 17 and 18 hereinabove, and further in view of U.S. Patent 5,897,515 to Willner et al. (hereinafter “Willner”), Claims 16 and 19-21 under 35 U.S.C. §103(a) as allegedly being unpatentable over Hall as applied to Claims 13, 17 and 18 hereinabove, and further in view of the publication WO

95/31950 and/or Willner and Claims 22-25 under 35 U.S.C. §103(a) as allegedly being unpatentable over Hall as applied to Claims 13, 17 and 18 hereinabove, and further in view of U.S. Patent 5,545,127 to William DeToro (hereinafter "DeToro") and/or U.S. Patent 5,486,157 to Anthony DiBenedetto (hereinafter "DiBenedetto"). Applicant respectfully disagrees.

### 35 U.S.C. §102

To anticipate a claim under 35 U.S.C. §102, a single source must contain all of the elements of the claim.<sup>1</sup> Moreover, the single source must disclose all of the claimed elements "arranged as in the claim."<sup>2</sup> Finally, missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.<sup>3</sup>

The Applicant respectfully asserts that Hall does not disclose an orthosis having an anterior longitudinal stiffener and a strut both of which are constructed from a reinforced resin such that the stiffener is inflexibly rigid and the strut is resiliently and flexibly configurable, as claimed in Applicants amended Claim 13. The Applicant supports this assertion by directing the Examiners attention to column 5, lines 25-34 of Hall, where it should be clear that Hall merely discloses a brace constructed of a moulded thermoplastic, where the brace may be flexible to allow a user to walk. In light of the above discussion, the Applicant asserts that Hall does not disclose all of the elements of Applicants amended Claim 13, as required by existing case law. Thus, the Applicant asserts that Hall cannot and does not anticipate Applicant's amended Claim 13. Moreover, the Applicant asserts that amended Claims 17 and 18 depend, either directly or indirectly, from amended Claim 13, and because amended Claim 13 is not anticipated by Hall, amended Claims 17 and 18 also cannot be anticipated by Hall.

### 35 U.S.C. §103

For an obviousness rejection under 35 U.S.C. §103 to be proper, the Patent Office must meet the burden of establishing a prima facie case of obviousness. Thus the Patent Office must meet the burden of establishing that all elements of the invention are disclosed in the prior art, that the prior art relied upon, coupled with knowledge generally available in the art at the time

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<sup>1</sup> *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q. 2d 1766, 1768 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988)

<sup>2</sup> *Structural Rubber Prods. Co., v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984)

<sup>3</sup> *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985)

the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combine references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.<sup>4,5,6</sup>

The Applicant asserts that Hall does not teach, and in fact teaches away from, an orthosis having an anterior longitudinal stiffener and a strut both of which are constructed from a reinforced resin such that the stiffener is inflexibly rigid and the strut is resiliently and flexibly configurable, as claimed in Applicants amended Claim 13. This is not possible with the brace disclosed in Hall. The Applicant supports this assertion by pointing out that the preferred embodiment of the brace disclosed by Hall is constructed from a moulded thermoplastic, a material known to have very low energy storage capabilities (see column 5, lines 12-35 of Hall). It is also known that such materials tend to degrade over time (resulting in a permanent deformation under a load), have a poor ability to retain a predefined shape and are subject to considerable variation in performance as the temperature varies.

The Applicants assertion is further supported by recognizing that Hall discloses and teaches a brace having a yoke or stirrup 30 with elongated side members 34, 36 that are wide in the fore and aft direction (See Figure 1 and Column 5, Lines 12-34 of Hall) and that are simply meant for supporting the foot pad while allowing for a controllable degree of flexibility (see Abstract and column 2, line 27 to column 3, line 60). This is a critical distinction because this means that the elongated side members 34, 36 are very resistant to bending, even if they are constructed from thin material. Thus, the Applicant asserts that this inherent rigidity, coupled with the thermoplastic construction, teaches away from an orthosis that is resiliently flexible for advantageously imparting a spring force to the foot of a user to assist the user to walk, as claimed in Applicants amended Claim 13 (see Page 6, 2<sup>nd</sup> full paragraph, Page 8, 3<sup>rd</sup> full paragraph, Page 9, 6<sup>th</sup> paragraph and Figure 3 of Applicants disclosure).

Therefore, in light of the above discussion the Applicant asserts that Applicants amended Claim 13 is patentably unobvious over Hall because there is no teaching, suggestion or motivation to modify the disclosure of Hall to obtain the orthosis as claimed in Applicants amended Claim 13. Moreover, the Applicant asserts that amended Claims 17 and 18 depend,

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<sup>4</sup> *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988)

<sup>5</sup> *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970)

either directly or indirectly, from amended Claim 13, and because amended Claim 13 is patentably unobvious over Hall, amended Claims 17 and 18 must also be patentably unobvious over Hall.

Regarding Claim 14, Applicant's attorney has been unable to locate any teaching, suggestion or motivation to combine WO 95/31950 with the teachings of Hall to obtain the orthosis of Applicants amended Claim 14. The Applicant asserts that although WO 95/31950 discloses the use of well known materials, WO 95/31950 discusses this use as a wrist orthosis and fails to disclose, teach or suggest how to use these materials in a useful combination to obtain the orthosis of Applicants amended Claim 14. Moreover, in light of the discussion above regarding Applicants amended Claim 13, the Applicant asserts that amended Claim 14 depends from amended Claim 13, and because amended Claim 13 is patentably unobvious over Hall, amended Claim 14 must also be patentably unobvious over Hall and thus, patentably unobvious over Hall in view WO 95/31950.

Regarding Claim 15, the Applicant asserts that amended Claim 15 depends from amended Claim 13, and because amended Claim 13 is patentably unobvious over Hall, amended Claim 15 must also be patentably unobvious over Hall and thus, patentably unobvious over Hall in view Willner.

Regarding Claims 16 and 19-21, the Applicant asserts that Claim 16 has been cancelled and that amended Claims 19-21 depend, either directly or indirectly, from amended Claim 13 and because amended Claim 13 is patentably unobvious over Hall, amended Claim 15 must also be patentably unobvious over Hall and thus, patentably unobvious over Hall in view Willner and/or the publication WO 95/31950.

Regarding Claims 22-25, the Applicant asserts that amended Claims 22-25 depend, either directly or indirectly, from amended Claim 13 and because amended Claim 13 is patentably unobvious over Hall, amended Claims 22-25 must also be patentably unobvious over Hall and thus, patentably unobvious over Hall in view DeToro and/or DiBenedetto.

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<sup>6</sup> *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996)

**CONCLUSION**

The Examiner is kindly invited to telephone the undersigned to resolve any questions in order to expedite the allowance of the pending claims. The listing of all claims is presented as a complete marked-up listing (without the clean version) in accordance with the Pre-OG Notice of the Office of Patent Legal Administration of 1-31-03

(<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>).

Respectfully submitted,



Mark S. Leonardo, Reg. No. 41,433  
Brown Rudnick Berlack Israels LLP  
One Financial Center, Box IP  
Boston, MA 02111  
Phone: 617-856-8145  
Fax: 617-856-8201  
Customer No. 21710

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